K012024

JUL 2 5 2001

Special 510(k) Device Modification:
EBI® XFIX® DFS® Fixation System

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI® XFIX® DFS® System is provided as required per Section 513(I)(3) of the Federal Food, Drug and Cosmetic Act.

1. **Sponsor:**
EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Patricia Flood, RAC
Telephone: (973) 299-9300, ext.3318

Date Prepared: June 27, 2001

2. **Proprietary Name:** EBI® XFIX® DFS® System

Common Name: External Fixation Device

Classification Name: Single Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR 888.3030.

3. **Predicate or Legally Marketed Device:**

- EBI® XFIX® DFS® System (K953406)

4. **Description of Device:**

The System consists of fixation components and implantable bone screws. The EBI® XFIX® DFS® System is utilized in the following manner: bone screws are inserted through the patient's skin and soft tissue, and into the bone. The fixator frame of the EBI® XFIX® DFS® System is attached to the shanks of the bone screws. The intended use and fundamental scientific technology have not changed from the previously cleared submission. This submission is only for the addition of a component to the System.

5. **Intended Use:**

The EBI® XFIX® DFS® System is a unilateral external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

6. Materials:

The components of the System may be manufactured from materials such as Aluminum, Stainless Steel, Cobalt Chrome, Carbon Fiber, and Titanium Alloy.

7. Comparison of the technological characteristics of the device to predicate devices:

The modified EBI® XFIX® DFS® System is substantially equivalent to the following predicate device:

EBI® XFIX® DFS® System (K953406)

- The modified EBI® XFIX® DFS® System is fabricated from the same materials as the components of the currently marketed EBI® XFIX® DFS® Fixation System.
- The modified EBI XFIX® DFS® System and the currently marketed EBI® XFIX® DFS® System are both indicated for the treatment of bone conditions, including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.
- The bone screw clamps of the modified EBI® XFIX® DFS® System, like the bone screw clamps currently marketed in the EBI® XFIX® DFS® System, are designed for attachment to the bone screws.
- The additional component of the EBI® XFIX® DFS® System, like the components of the currently marketed EBI® XFIX® DFS® System, is provided non-sterile.
- There are no significant differences between the modified EBI® XFIX® DFS® System and the currently marketed EBI® XFIX® DFS® System. It is substantially equivalent* to the predicate device with regard to intended use, materials, and function.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2001

Ms. Patricia Flood, RAC
Senior Regulatory Affairs Specialist
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K012024
Trade/Device Name: EBI® XFIX® DFS® System
Regulation Number: 888.3030
Regulatory Class: II
Product Code: KTT
Dated: June 27, 2001
Received: June28, 2001

Dear Ms. Flood:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known):

Device Name: EBI® XFIX® DFS® System

Indications For Use:

The EBI XFIX® DFS® System is a unilateral external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012024